DPF submitted deregulation form on 5/16/25

Which agency/agencies promulgated the regulation?

DEA

Which title, parts, and/or sections of the Code of Federal Regulations (C.F.R.) should be rescinded?

Title 21, Part 1306, Section 1306.04(a)

What is the name of the regulation being rescinded, if applicable?

Purpose of issue of prescription

Please provide a short summary of the justifications for the rescission?

21 CFR §1306.04(a) allows the DEA to determine whether a controlled substance prescription is issued for a "legitimate medical purpose," but the regulation lacks objective criteria. In recent years, the DEA has used this vague language to prosecute physicians based on arbitrary dosage thresholds, particularly those borrowed from the CDC's 2016 opioid guideline, which was never intended for enforcement. Physicians have been raided, arrested, or lost their licenses for prescribing above morphine milligram equivalent (MME) limits, even when treating stable patients with no evidence of diversion or harm.

Because this regulation gives the DEA wide discretion, many doctors are cutting patients off medications out of fear, not based on clinical judgment. When a provider retires, dies, or is shut down, other clinicians are often too afraid to take the patient on, knowing that continuing opioid therapy might expose them to regulatory or criminal risk. This leads to widespread medical abandonment.

The result is a national crisis: millions of stable, compliant patients are being left with no safe options and forced into painful withdrawal, considering suicide, or turning to the illicit drug supply to survive.

Importantly, the Supreme Court's 2022 decision in *Ruan v. United States* clarified that, under the Controlled Substances Act, the government must prove a doctor knowingly or intentionally acted without legitimate medical purpose. Despite this ruling, DEA and DOJ continue to enforce 21 CFR §1306.04(a) as if intent does not matter, treating dosage thresholds and guideline violations as criminal conduct in and of themselves.

This regulation is now being enforced in a way that directly contradicts a unanimous Supreme Court decision. Even though *Ruan* was a 9–0 ruling, federal prosecutions continue to rely on the same pre-*Ruan* interpretation, effectively ignoring the Court's clear requirement to prove criminal intent.

Please insert the address of the agency. [NPRM, DFR, and IFR only]

Drug Enforcement Administration

Office of Diversion Control

Attn: Regulatory Drafting and Policy Support Section

8701 Morrissette Drive

Springfield, VA 22152

Agency Name:

Drug Enforcement Administration (DEA)

Office of Diversion Control

Regulatory Drafting and Policy Support Section

What is the background for the regulation being rescinded?

21 CFR §1306.04(a) is a long-standing regulation under the Controlled Substances Act (CSA), originally created to ensure that prescriptions for controlled substances are written for a legitimate medical purpose by practitioners acting in the usual course of professional practice. The language is intentionally broad and does not define specific medical criteria, leaving interpretation to the Drug Enforcement Administration (DEA) and the courts.

Historically, this regulation was used to target clear cases of diversion or "pill mill" operations. However, in the past decade particularly following the CDC's publication of the 2016 Guideline for Prescribing Opioids for Chronic Pain, the DEA began to apply §1306.04(a) much more aggressively. Federal prosecutors and regulatory authorities began treating dosage thresholds, especially the 90 morphine milligram equivalents (MME)

recommendation in the CDC guideline, as hard legal limits, despite CDC's clarification that its guidance was not intended to serve as regulatory or enforcement standards.

As a result, 1306.04(a) has evolved into a de facto criminal statute used to penalize prescribers for deviating from federal guidance, even in the absence of diversion, patient harm, or intent to misuse. Physicians have been prosecuted or sanctioned for exceeding subjective thresholds, treating pain with individualized regimens, or continuing therapy for long-term patients whose care predated the CDC guidelines.

In 2022, the U.S. Supreme Court issued a unanimous ruling in Ruan v. United States, holding that, under the CSA, the government must prove beyond a reasonable doubt that a prescriber knowingly or intentionally acted without a legitimate medical purpose. The Court rejected the DEA's prior interpretation that physicians could be prosecuted based solely on deviation from norms or guidelines.

Despite this landmark ruling, 21 CFR §1306.04(a) has not been amended, and DEA continues to operate as though Ruan never occurred. The agency still uses guideline deviations and dosage thresholds as proxies for illegitimacy, without proving criminal intent. This regulatory disconnect has led to widespread confusion, defensive medicine, and fear among providers. Many doctors now refuse to treat pain patients or taper long-standing prescriptions, leading to mass medical abandonment, withdrawal crises, and suicide.

Because 1306.04(a) remains unchanged, its vague wording continues to be interpreted in ways that directly contradict Ruan, ignore current clinical science, and create a dangerous climate of fear and confusion in pain care.

Explain the reasons for the rescission.

The regulation found in **21 CFR §1306.04(a)** must be rescinded or fundamentally revised for the following reasons:

1. The Regulation Is Now Inconsistent with Binding Supreme Court Precedent

In Ruan v. United States (2022), the U.S. Supreme Court ruled unanimously that the Controlled Substances Act (CSA) requires the government to prove that a physician "knowingly or intentionally" acted without a legitimate medical purpose when prescribing controlled substances. This established a mens rea (criminal intent) requirement for prosecutions under the CSA.

However, 21 CFR §1306.04(a) remains vague and continues to be interpreted by the DEA and DOJ as allowing strict liability enforcement, meaning providers can be criminally charged simply for violating subjective dosage thresholds, without evidence of criminal intent. This contradicts Ruan directly. Enforcing this regulation without proof of intent is unlawful.

2. The Regulation Is Inconsistent with Due Process Under the Constitution

The lack of objective criteria in §1306.04(a) renders it unconstitutionally vague. Physicians are given no clear standards to follow, only the threat that if their prescribing differs from guidance documents like the CDC's 2016 or 2022 opioid guidelines, they may be investigated, charged, or imprisoned.

This violates the Fifth Amendment's Due Process Clause, which requires laws to give people fair notice of what conduct is prohibited and to avoid arbitrary enforcement. Doctors are being criminalized for what were once routine medical practices, based on shifting interpretations and prosecutorial discretion.

3. The Regulation's Costs Far Outweigh Any Claimed Benefits

The chilling effect of §1306.04(a) on legitimate medical practice has led to:

- Mass discontinuation or forced tapering of opioid therapy,
- Widespread patient abandonment,
- A rise in suicides and overdoses following loss of care,
- Fear among prescribers that has emptied entire regions of pain care access.

No benefit, including the deterrence of criminal prescribing, justifies these outcomes, especially since genuine diversion can still be prosecuted under existing criminal statutes without relying on this vague standard.

4. The Regulation No Longer Reflects Current Scientific and Legal Understanding

Modern pain science, addiction research, and federal policy consensus now recognize that one-size-fits-all dosage thresholds are not clinically appropriate. The CDC itself has clarified that its 90 MME threshold was never meant to be a hard limit or used for enforcement. Yet DEA continues to use it as a proxy for criminality under §1306.04(a).

Moreover, since the regulation predates both the epidemic of medical abandonment and the Supreme Court's ruling in Ruan, it no longer reflects legal or clinical reality.

5. The Regulation Is Bad Policy and Has Led to Unintended, but Catastrophic Consequences

What began as a safeguard against diversion has now become a weapon against ethical providers. The DEA's reliance on §1306.04(a) has resulted in:

- Doctors avoiding high-risk patients,
- Providers exiting the field,
- Patients forced into illicit drug markets,
- Avoidable deaths due to abrupt discontinuation or suicide.

This regulation is no longer protecting public safety, it is actively endangering it.

Rescinding or substantially revising 21 CFR §1306.04(a) is necessary to bring DEA enforcement practices into compliance with constitutional protections, Supreme Court precedent, and modern medical standards. Failure to act will perpetuate a public health and civil rights crisis affecting millions of Americans who live with pain.

Describe the text of the relevant C.F.R. provisions as it will exist after the rescission.

I am requesting substantial revision, rather than full rescission, of 21 CFR §1306.04(a) to align it with the unanimous U.S. Supreme Court decision in Ruan v. United States (2022) and to prevent further misuse of the regulation that is contributing to widespread patient abandonment and physician fear. Below is proposed replacement language that would preserve the DEA's ability to address true diversion, while protecting ethical medical decision-making and ensuring constitutional due process:

§1306.04(a) Purpose of issue of prescription.

A prescription for a controlled substance must be issued by a practitioner in the usual course of professional practice and for a legitimate medical purpose.

The determination of whether a prescription is for a legitimate medical purpose shall be based on the practitioner's intent and good faith belief, consistent with generally accepted medical standards and individual patient needs.

The presence of high dosage levels, long-term therapy, concurrent use with other medications, or deviation from federal guidelines shall not, on their own, constitute evidence of criminal conduct or lack of legitimacy.

No prescriber shall be subject to civil or criminal penalties under this section unless the government proves beyond a reasonable doubt that the practitioner knowingly or intentionally acted outside the bounds of medical practice and without a legitimate medical purpose.

This section shall be interpreted in a manner consistent with the U.S. Supreme Court's ruling in Ruan v. United States, 597 U.S. ___ (2022).